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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/592,946	09/15/2006	Seong-Lok Hwang	36470-236071	8697

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EXAMINER

CHEN, CATHERYNE

ART UNIT	PAPER NUMBER
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1655

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/592,946	Applicant(s) HWANG ET AL.	
	Examiner CATHERYNE CHEN	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Currently, Claims 11-25 are pending. Claims 11-25 are examined on the merits.

Election/Restrictions

Applicant's election of the species lower alcohol, Sophorae Radix, Hinokition, capsicum tincture, in the reply filed on Oct. 22, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and the breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Limited amount of guidance and limited number of working examples in the specification

While the Specification recited complications of hair loss, there is only one type of hair loss recited in page 1, lines 18-26). No other types of hair loss are cited.

Nature of the invention

There are many types of hair loss. Hair loss can be due to male sex hormones, excessive sebum secretion, poor blood circulation, scalp dysfunction, bacteria, hereditary factors, aging, stress, cancer therapy. Thus it would be impossible to prevent someone from getting hair loss when one is genetically disposed (see <http://www.webmd.com/skin-problems-and-treatments/hair-loss/tc/hair-loss-prevention>).

State of the prior art

There are many causes of hair loss. Hair loss can be due to male sex hormones, excessive sebum secretion, poor blood circulation, scalp dysfunction, bacteria, hereditary factors, aging, stress, cancer therapy.

Relative skill level of those in the art

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Those in the art would have a difficult time to treat hair loss because of the many causes of hair loss. Therefore, the relative skill level required would be high.

Predictability or unpredictability in the art

Because of the many causes of hair loss, the unpredictability in the art would be high.

The breadth of the claims

The breadth of the claims is broad, particularly for hair loss prevention.

Applicant's claims are broadly drawn to a composition that is able to prevent hair loss. In order to be enabled for prevention of a condition, applicant must demonstrate that the invention is able to prevent the condition each and every instance of that condition. Applicant's specification does not set forth any evidence that the claimed product is able to prevent hair loss for all potential causes of hair loss. In addition, the art teaches hair loss prevention is not accepted as possible because many risk factors such as age, race and family history cannot be controlled (see <http://www.webmd.com/skin-problems-and-treatments/hair-loss/tc/hair-loss-prevention>). Because applicant's specification does not show prevention of hair loss and the art acknowledges that prevention is not currently possible, a person of ordinary skill in the art would be forced to experiment unduly in order to determine if applicant's invention actually functions as claimed. Therefore, the claims are not considered enabled for the prevention of hair loss.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bak et al. (KR 1020010003366 A).

Bak et al. teaches a hair tonic composition containing Asarum sieboldii to activate the root of hair, feed nutrients to hair, and accelerate blood circulation (Abstract). Asiasari radix is also known as Asarum sieboldii (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>).

Claims 11-12, 20, 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuen (US 6027728).

Yuen teaches composition with 6% wt Sophora Flavescens and 6% wt Asarum Chinese Wild Ginger (column 3, lines 49-50) for application to skin (column 7, line 5). Asiasari radix is also known as Asarum Chinese Wild Ginger (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>).

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Claims 11-14, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishida et al. (JP 61212513 A).

Ishida et al. teaches ethanol extract of saishin or *Asiasarum sieboldi*, where 0.5% wt of the extract is used (Abstract). *Asiasari radix* is also known as *Asarum sieboldii* (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>).

Claims 11, 18, 20, 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahn et al. (KR 2002025152 A).

Ahn et al. teaches composition to fight dandruff with capsicum and *Asarum heterotropoides* (Abstract). *Asiasari radix* is also known as *Asarum heterotropoides* (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>).

Claims 11, 15, 16, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Asano et al. (JP 2000119156 A).

Asano et al. teaches topical composition for skin with *Sophora flavescens*, *Asiasarum sieboldii*, cypress (for hinokitiol) (Abstract). *Asiasari radix* is also known as *Asarum sieboldii* (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>). *Sophorae Radix* is also known as *Sophora flavescens* (see http://www.fzrm.com/plantextracts/Lightyellow_Sophora_Root_extract.htm). Hinokitiol is

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present in cypress (see Abstract, Suzuki, 2000, Biochem Biophys Res Comm, 275, 885-889).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-12, 16-17, 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takekoshi et al. (US 6497889 B2).

Takekoshi et al. teaches cosmetic with hinokitiol, *Sophora flavescens*, *Asarum sieboldii* (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). *Asiasari radix* is also known as *Asarum sieboldii* (see <http://www.naturalstandard.com/index-abstract.asp?create->

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[abstract=/monographs/herbssupplements/patient-asarum.asp](#)). Sophorae Radix is also known as *Sophora flavescens* (see http://www.fzrm.com/plantextracts/Lightyellow_Sophora_Root_extract.htm). However, it does not teach all the composition together.

The reference does not teach all of the claimed ingredients in one composition. However, the reference does teach that each of the claimed ingredients is suitable for combination in a pharmaceutical composition. Thus, an artisan of ordinary skill would be reasonably expected that the claimed ingredient could be combined together to produce a single pharmaceutical product. This reasonable expectation of success would motivate the artisan to combine the claimed ingredients together into a single composition.

Claims 11-12, 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takekoshi et al. (US 6497889 B2) as applied to claims 11-12, 16-17, 20 above, and further in view of Kim (KR 1020000038214 A).

Takekoshi et al. teaches cosmetic with hinokitiol, *Sophora flavescens*, *Asarum sieboldii* (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). *Asiasari radix* is also known as *Asarum sieboldii* (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>). *Sophorae Radix* is also known as *Sophora flavescens* (see

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http://www.fzrm.com/plantextracts/Lightyellow_Sophora_Root_extract.htm). However, it does not teach capsicum tincture and concentrations.

Kim teaches a hair growth composition with capsicum tincture and hinokitiol (Abstract).

The references do not specifically teach combining capsicum tincture and Sophorae radix and Asiasari radix together. The references do teach that the ingredients are used for hair care (see discussion above). As discussed in MPEP 2144.06:

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.

Thus, it would be obvious to combine capsicum tincture with Sophorae radix Asiasari radix because they are taught in the reference to have the same purpose.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. However, the references do teach the composition for hair care. Takekoshi et al. teaches cosmetic with hinokitiol, Sophora flavescens, Asarum sieboldii (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). Kim teaches a hair growth composition with capsicum tincture and hinokitiol (Abstract). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient)

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is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claims 11-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takekoshi et al. (US 6497889 B2) and Kim (KR 1020000038214 A) as applied to claims 11-12, 15-20 above, and further in view of Ishida et al. (JP 61212513 A).

Takekoshi et al. teaches cosmetic with hinokitiol, *Sophora flavescens*, *Asarum sieboldii* (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). *Asiasari radix* is also known as *Asarum sieboldii* (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>). *Sophorae Radix* is also known as *Sophora flavescens* (see http://www.fzrm.com/plantextracts/Lightyellow_Sophora_Root_extract.htm). However, it

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does not teach capsicum tincture, concentrations, and lower alcohol extract of Asiasari Radix.

Kim teaches a hair growth composition with capsicum tincture and hinokitiol (Abstract).

Ishida et al. teaches ethanol extract of saishin or Asiasarum sieboldi, where 0.5% wt of the extract is used (Abstract). Asiasari radix is also known as Asarum sieboldii (see <http://www.naturalstandard.com/index-abstract.asp?create-abstract=/monographs/herbssupplements/patient-asarum.asp>).

Takekoshi et al. teaches cosmetic with hinokitiol, Sophora flavescens, Asarum sieboldii (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). Kim teaches a hair growth composition with capsicum tincture and hinokitiol (Abstract). Ishida et al. teaches ethanol extract of saishin or Asiasarum sieboldi, where 0.5% wt of the extract is used, on skin (Abstract). Hair is attached to skin. When one washes hair, skin attached to the hair is also being washed. Thus, an artisan of ordinary skill would reasonably expect that hinokitiol, Sophora flavescens, ethanol extract of Asarum sieboldii, capsicum tincture could be used as the types hair care ingredient taught by the references. This reasonable expectation of success would motivate the artisan to use ethanol extract of the same ingredient in the reference composition. Thus, using all the claimed ingredients is considered an obvious modification of the references.

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The references do not specifically teach adding the ingredients in the amounts claimed by applicant. However, the references do teach the composition for hair care. Takekoshi et al. teaches cosmetic with hinokitiol, *Sophora flavescens*, *Asarum sieboldii* (column 7, lines 27, 53, 56-57), components at 0.01-5wt % for use as hair care cosmetic, hair shampoo, hair rinse, hair conditioner, hair nourishing agent, hair-growing agent (column 8, lines 32-50). Kim teaches a hair growth composition with capsicum tincture and hinokitiol (Abstract). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Conclusion

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catheryne Chen whose telephone number is 571-272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/

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Primary Examiner, Art Unit 1655